there is tension between the antitrust laws' objective of enhancing competition by preventing unlawful monopolies and patent laws' objective of incentivizing innovation by granting legal patent monopolies. *See In re Adderall*, 754 F.3d at 133; *see also SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1205 (2d Cir. 1981).

But in its recent landmark antitrust case, *F.T.C. v. Actavis, Inc.*, the Supreme Court made clear that "patent and antitrust policies are both relevant in determining the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent." 133 S. Ct. at 2231 (internal quotation marks omitted); *see also United States v. Gypsum Co.*, 333 U.S. 364, 390–91 (1948) (indicating that courts must "balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize").

The Court's decision in *Actavis* reaffirmed the conclusions of circuit courts that a patent does not confer upon the patent holder an "absolute and unfettered right to use its intellectual property as it wishes," *Microsoft*, 253 F.3d at 63, and "[i]ntellectual property rights

do not confer a privilege to violate the antitrust laws," *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000). *See also Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 998 (9th Cir. 2010) ("[C]hanges in product design are not immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2.").

Defendants argue that their conduct does not violate antitrust law because they have merely "exercised rights afforded by the Patent Act." Defs. Br. at 34. But patent law gives Defendants a temporary monopoly on individual drugs—not a right to use their patents as part of a scheme to interfere with competition "beyond the limits of the patent monopoly." *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948). Defendants have essentially tried to use their patent rights on Namenda XR to extend the exclusivity period for all of their memantine-therapy drugs. As explained above, it is the *combination* of Defendants' withdrawal of IR and introduction of XR in the context of generic substitution laws that places their

conduct beyond the scope of their patent rights for IR or XR individually.

IV. The Sherman Act § 1 and the Donnelly Act

In light of New York's substantial likelihood of success on the merits of its monopolization and attempted monopolization claims, we need not address the merits of its Sherman Act § 1 or Donnelly Act claims, which are based on the agreement between Defendants and Foundation Care. We do note, however, that an agreement related to a party's violation of § 2 does not trigger liability under § 1 unless the agreement *itself* unreasonably restrains trade, *Geneva Pharm.*, 386 F.3d at 506, and there is mutual anticompetitive intent, *see id.* at 507 ("[L]ack of intent by one party . . . precludes a conspiracy to monopolize."). Conduct that satisfies the unreasonable restraint prong under § 2 does not necessarily violate § 1 absent evidence that the agreement furthers the anticompetitive conduct. *Id.* at 506.

V. Irreparable Harm

New York has made a "strong" showing that competition and consumers will suffer irreparable harm in the absence of the injunction. *Doe*, 666 F.2d at 773. Irreparable harm is "injury that is neither remote nor speculative, but actual and imminent and that cannot be remedied by an award of monetary damages." *Forest City Daly Hous., Inc. v. Town of N. Hempstead*, 175 F.3d 144, 153 (2d Cir. 1999) (internal quotation marks omitted). To obtain injunctive relief under § 16 of the Clayton Act, that injury must be an injury "of the type the antitrust laws were designed to prevent and that flows from that which makes defendants' acts unlawful." *Consol. Gold Fields PLC v. Minorco, S.A.*, 871 F.2d 252, 257 (internal quotation marks omitted), *amended by* 890 F.2d 569 (2d Cir. 1989).

As the district court concluded, "[p]ermanent damage to competition in the memantine market can . . . result from Defendants' planned hard switch strategy."[32] S.A. 131. If generics

[32] *See also LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003) ("When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, i.e.

cannot compete with Defendants' drugs via state substitution laws, they "cannot compete effectively for sales of a branded drug in the same class, such as Namenda XR, even if the price of the generics is much lower than the brand." S.A. 80-81; *see also* IP and Antitrust Prof. Br. at 13-14 (explaining that absent substitution at the pharmacy, "the market for generics will collapse"). Moreover, generics cannot simply move into the market for generic XR. To become substitutable for Namenda XR, generic manufacturers must develop new once-daily Namenda tablets, begin the ANDA-approval process all over again, and await the end of XR's patent exclusivity period in 2029. Because Defendants' conduct does not simply harm a competitor or two, but threatens to "reduce competition in the [memantine-drug] market[,] . . . [it] is precisely the type that the antitrust laws were designed to protect against." *Consol. Gold*, 871 F.2d at 257-58.

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predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general.").

The district court also found that, in addition to harming consumer choice, Defendants' hard switch would cause economic harm to consumers. Based on Defendants' own data, the district court found that consumers would pay almost $300 million more and third-party payors would pay almost $1.4 billion more for memantine therapy if Defendants were permitted to switch patients to Namenda XR before generic IR entry. And HHS reports that Defendants' withdrawal of Namenda IR prior to generic entry would cost Medicare and its beneficiaries a minimum of $6 billion over the next ten years.[33] "Threaten[ed] economic harm to . . . consumers . . . is plainly sufficient to authorize injunctive relief." *Am. Stores Co.*, 495 U.S. at 283.[34]

Defendants argue that the district court erred in finding *irreparable* harm because any increase in costs to consumers and third-party payors is "compensable and readily quantifiable." Defs. Br. at 26. But compensating the approximately 500,000 Alzheimer's

[33] HHS, *Some Observations*, at 7.

[34] Given that we conclude that the district court did not abuse its discretion in granting a preliminary injunction based on the harm to competition and economic harm to consumers, we need not consider whether the district court's findings related to medical harm to patients provided a basis for injunctive relief.

patients who take Namenda IR tablets, and an unknown number of public and private third-party payors, for an ongoing harm would impose "the task of disentangling overlapping damages claims [which] is not lightly to be imposed upon potential antitrust litigants, or upon the judicial system." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 475 n.11 (1982); *see also Salinger v. Colting*, 607 F.3d 68, 81 (2d Cir. 2010) ("Harm might be irremediable, or irreparable, for many reasons, including that a loss is difficult to replace . . . .").[35] In

[35] Defendants also argue that the district court erred in discounting the harm that they will suffer as a result of the injunction. We need not consider the balance of the hardships given that New York has demonstrated a substantial likelihood of success on the merits. In any event, we agree with the district court that the balance of the hardships tips decidedly in New York's favor.

Defendants argue that they will be injured if they cannot convert patients to Namenda XR prior to July 2015, but that argument begets the question of whether their conduct is lawful. Certainly, courts do not consider the harm a party suffers from being prevented from violating the law.

Defendants also argue that they "had stopped making IR batches and ha[d] been implementing plans to limit distribution for months." Defs. Br. at 25. Ordering Defendants to manufacture IR, Defendants argue, impedes production of XR and delays the development of Namzaric, an even newer Alzheimer's drug, because the FDA has only certified one plant to produce IR, XR, and Namzaric. This argument is belied by the record. At the preliminary injunction hearing, one of Defendants' executives testified that the plant could manufacture IR while manufacturing XR. J.A. 533. Defendants also informed the district court that there was no cap on the amount of IR that would be supplied through Foundation Care and that the supply could be "adjusted as necessary based on demand." J.A. 904. Another of Defendants' experts testified that the "biggest problem [Defendants] have with [manufacturing both IR and XR] is the labor force," but "the equipment is completely different equipment." J.A. 202. Defendants' expert clarified that they need skilled labor but, at most, he

addition, many of the victims of Defendants' hard switch, such as patients and health plans, may be prevented from direct recovery for their antitrust losses because of the "indirect purchaser" rule, which bars those who do not directly purchase a product from recovering antitrust damages, thus further supporting New York's claim of irreparable injury. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 745-46 (1977).

Additionally, we agree with the district court, and the parties do not dispute, that the preliminary injunction serves the public's interest in a competitive market for memantine drugs. *See United States v. Siemens Corp.*, 621 F.2d 499, 506 (2d Cir. 1980) (finding that the government represents the public's interest in a competitive marketplace in seeking to enjoin a merger under § 7 of the Clayton Act); *see also Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 424 (2d Cir. 2004) ("[G]overnment action taken in furtherance of a regulatory or statutory scheme . . . is presumed to be in the public interest").

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explained that there might be some delay caused by training employees to use the new XR equipment where employees who had manufactured IR would be able to transition more quickly. J.A. 203.

VI. The Preliminary Injunction

Defendants argue that the injunction provision requiring them to make Namenda IR tablets available on the same terms and conditions applicable since July 21, 2013 is vague because the terms and conditions have shifted over the past 17 months. We disagree. The injunction plainly prohibits Defendants from charging more for Namenda IR than it did during the specified timeframe and from restricting access to IR. If Defendants need additional clarification, they can seek it in the district court.

Defendants also argue that the injunction is overbroad because there is no antitrust violation in the 20 states in which drug substitution laws *might* allow pharmacists to substitute generic IR for Namenda XR. Defendants did not raise this argument before the district court, and therefore have forfeited it. *See, e.g., Zalaski v. City of Hartford*, 723 F.3d 382, 395 (2d Cir. 2013) ("[P]laintiffs failed to raise the argument in the district court, thereby forfeiting it on appeal."). In any event, that argument is not persuasive because, as explained above, it exaggerates the extent to which state substitution

laws differ. Defendants have not brought to our attention a single state in which drug substitution laws will definitively allow pharmacists to submit generic IR for Namenda XR, and have thus failed to identify any state for which there is no antitrust violation.

CONCLUSION

For the reasons stated above, we AFFIRM the District Court's order granting New York's motion for a preliminary injunction.

EXHIBIT 106

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff,

14 Civ. 7473

-against-

OPINION

ACTAVIS, PLC, and
FOREST LABORATORIES, LLC,

Defendants.

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Sweet, D.J.

The plaintiff, the People of the State of New York (the "State" or the "Plaintiff"), has moved pursuant to Rule 65 of the Federal Rules of Civil Procedure to preliminarily enjoin the defendants, Actavis, PLC ("Actavis") and Forest Laboratories, LLC ("Forest") (collectively, the "Defendants"), from engaging in antitrust violations by discontinuing the current sales of the Forest drug Namenda IR, used in the treatment of Alzheimer's disease, currently scheduled to take effect on January 1, 2015. Based on the findings of fact and conclusions of law set forth below, the motion is granted, and a preliminary injunction will issue.

This motion involves one piece of the complicated mosaic that is the health care sector in the United States. At issue is the competition between Forest, a manufacturer of branded and patented drugs to treat Alzheimer's disease, and manufacturers that produce generic equivalents, as well as the effect of that competition on consumers. This competition has been the subject of federal and state legislation and is of great importance to pharmaceutical companies, patients, physicians, pharmacists, insurers, health plans, and regulators.

The issue is significant because of the particular needs of patients afflicted by Alzheimer's, the process by which prescription drugs are created and sold, and the economic significance of Forest's Namenda drugs, which had annual sales of over $1.5 billion in last year.

The idiosyncrasies of competition in this market were captured by the State's expert, Dr. Ernst Berndt:

> I think the phrase goes, he who consumes doesn't pay, and he who buys is not held accountable. . . . So we have this multiplicity of prices. We have the price received by the manufacturer and we have the total revenues received by the pharmacy. And we have the reimbursement to the pharmacy and a copayment by the patient. Who the consumer is ultimately a bit ambiguous.

Tr. 368:1-7 (Berndt).

Able and skilled counsel have assisted the court with their presentations of the complicated and significant issues raised by the State's antitrust and state law violation claims. In addition, this excellent performance has been rendered under the difficult conditions imposed by the march of time and the controlling external events.[1]

[1] The calendar has also dictated the timing of the issuance of this opinion. While the issues are deserving of an exhaustive treatment, their significance requires resolution in time to permit the possibility of appellate review.

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Prior Proceedings

On February 28, 2014, the Antitrust Bureau of the Office of the Attorney General of the State of New York (the "Bureau") opened an investigation into Forest's business plans regarding the pharmaceutical product Namenda, a therapy approved to treat Alzheimer's disease by the Food and Drug Administration ("FDA").

The State filed an initial complaint on September 15, 2014, followed by an Amended Complaint ("AC") on November 5, 2014, alleging that Defendants violated federal and state antitrust laws by attempting to improperly maintain and extend a monopoly over the Namenda drug. The AC sought injunctive relief requiring Defendants to keep the original form of the drug, Namenda IR, available on the market and to prevent the Defendants from in effect requiring patients to switch a new patent-protected form, Namenda XR.

The AC contains allegations describing: the parties (AC ¶¶ 12-15); the regulatory framework and relevant federal regulations, including the Food Drug and Cosmetic Act, 21 USC § 301 et seq., the Drug Price Competition and Patent Term

Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (AC ¶¶ 16-20); state generic substitution laws (AC ¶¶ 21-27); and the effect of generic competition and brand name manufacturers' tactics to evade them (AC ¶¶ 28-43).

The AC also contains allegations with respect to: Alzheimer's disease and the relevant products (AC ¶¶ 44-45); and the relevant market (AC ¶¶ 46-63), including memantine that is branded and marketed as Namenda by Defendants; Namenda's recent annual sales in excess of $1.5 billion in the United States; the extension of the Namenda patent; and the anticipated entry of generic competition in July 2015. The AC further alleges that the Defendants have made efforts to stall the effects of generic entry in the market (AC ¶¶ 64-97), including the launch of Namenda XR in June 2013 and the effort to convert patients from Namenda IR to Namenda XR and the implementation and subsequent modification of a scheme to force patients to switch to the new formulation. The AC alleges the anticompetitive effect of the conduct of the Defendants (AC ¶¶ 98-104) and their conduct in exaggerating the imminence of the plan to force switches (AC ¶¶ 105-119).

Six causes of action are alleged: (1) monopolization in violation of Section 2 of the Sherman Act; (2) attempted monopolization in violation of Section 2 of the Sherman Act; (3) unreasonable restraint of trade in violation of Section 1 of the Sherman Act; (4) violation of the Donnelly Act, New York General Business Law Section 340 et seq.; (5) repeated or persistent illegality in violation of Section 63(12) of the New York Executive Law; and (6) repeated or persistent fraud, in violation of Section 63(12) of New York Executive Law.

The AC seeks: (i) a decree that Defendants violated the statutory provisions in the six causes of action outlined above; (ii) disgorgement of proceeds from illegal activity, repayment of monies gained from unjust enrichment, and payment of restitution and damages to injured parties; (iii) preliminary and permanent injunctive relief barring Defendants from discontinuing Namenda IR until generic memantine becomes available, barring Defendants from other violations of law and other equitable relief necessary to redress Defendants' purported violations of law; (iv) civil penalties, damages and restitution for violations of state laws, including the Donnelly Act; and (v) attorneys' fees.

The State moved pursuant to Rule 65 of the Federal Rules of Civil Procedure for a preliminary injunction. The motion was heard and evidence adduced from November 10 to November 14, 2014, and final arguments were heard and the motion was marked fully submitted on November 24, 2014.

Certain materials submitted to the Court have been designated confidential. In order to protect that confidentiality, a public version of this opinion will not be filed for twenty-four hours to give the parties an opportunity to request redactions.

Evidence

The following witnesses provided live or written testimony with respect to these proceedings:

Dr. Ernst Berndt ("Dr. Berndt")	Louis E. Seley Professor of Applied Economics at the Massachusetts Institute of Technology
Mr. Dan Blakely, R.Ph. ("Blakely")	Chief Executive Office of Foundation Care (an Actavis Vendor)
Mr. Napoleon Clark ("Clark")	Executive Director for Marketing - U.S. Generics at Actavis
Dr. Pierre Y. Cremieux ("Dr. Cremieux")	Managing Principal at Analysis Group
Mr. Mark Devlin ("Devlin")	Senior Vice President Managed Markets at Actavis
Ms. Babette Edgar ("Edgar")	Principal at BluePeak Advisors
Dr. Steven Ferris ("Dr. Ferris")	Gerald D. and Dorothy R. Friedman Professor of New York University's Alzheimer's Disease Center
Mr. Jason Harper ("Harper")	Director of Marketing at Mylan Pharms.
Dr. Jerry Hausman ("Hausman")	McDonald Professor of Economics at Massachusetts Institute of Technology
Dr. Alan Jacobs ("Dr. Jacobs")	Neurologist in private practice
Mr. William Kane ("Kane")	Vice President of Marketing Internal Medicine at Actavis
Dr. Bruce Kohrman ("Kohrman")	Neurologist in private practice
Dr. E. Mick Kolassa ("Dr. Kolassa")	Chairman and Managing Partner of Medical Marketing Economics
Dr. James J. Lah, MD, PhD ("Dr. Lah")	Associate Professor of Neurology at Emory University Medical Center Director of Emory Cognitive Neurology Program Associate Director of Alzheimer's Disease Research Center
Mr. William Meury ("Meury")	Executive Vice-President of Commercial Operations for the North American Brands Division at Actavis
Ms. LuMarie Polivka-West ("Polivka-West")	Vice-President and Senior Director of Policy and Program Development for the Florida Health Care Association
Dr. Barry Reisberg ("Dr. Reisberg")	Psychiatrist, Alzheimer's Disease Center of the New York University Langone Medical Center
Dr. Barry Rovner ("Dr. Rovner")	Professor of Psychiatry and Neurology at the Signey Kimmel Medical College of Thomas Jefferson University

Mr. Brenton Saunders ("Saunders")	Chief Executive Officer of Actavis (former Chief Executive Officer of Forest Labs.)
Mr. David F. Solomon ("Solomon")	Partner at Hildred Capital Partners, LLC (former Senior Vice President of Corporate Development and Strategy of Forest Labs.)
Mr. Robert Stewart ("Stewart")	Chief Operating Officer of Actavis
Mr. David F. Stitt, R. Ph. ("Stitt")	Director of Pharmacy at a New York-based health plan (MVP Health Care)
Dr. Marco Taglietti ("Dr. Taglietti")	Senior Vice President for Research & Development at Actavis
Mr. Kevin Walsh ("Walsh")	Senior Vice-President of Operations at Actavis

In addition to live witness testimony, the State presented 581 exhibits and the Defendants presented 835. One hundred fifty-one exhibits were referenced during the testimony of the witnesses.

Findings of Fact

I. The Parties

1. The State, by its Attorney General, brought this action in its capacity as parens patriae and also as an "indirect purchaser of Namenda." Amended Complaint ("AC") ¶ 9.

2. Defendant Actavis is a public limited company registered in Ireland and headquartered at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. It manufactures and sells generic drugs. In July 2014, Actavis acquired Forest. Tr. 192:8-10 (Saunders). Forest is a Delaware limited liability company with an office at Morris Corporate Center, 400 Interpace Parkway, Parsippany, New Jersey and at various New York locations. It manufactures and sells a number of branded pharmaceutical products including memantine hydrochloride (HCL) drugs in the form of Namenda IR tablets, Namenda IR oral solution, and Namenda XR capsules. See Press Release, Forest Labs., Forest Laboratories to Discontinue NAMENDA Tablets, Focus on Once-Daily NAMENDA XR (DX499) (Feb. 14, 2014). Defendants' United States revenues from Namenda were approximately $1.6 billion in Forest's 2014 fiscal year, and total sales stand to grow

consistent with the epidemiological projection that the number of Americans living with Alzheimers will triple by 2050. Tr. 612:16-22 (Meury); Forest 10-K (PX48) at 56; Rovner (PX358) ¶ 20.

II. Background

A. Alzheimer's Disease

3. As Dr. Ferris testified, "Alzheimer's disease is a progressive, irreversible, incurable disease of the brain that is the most common cause of dementia worldwide." Ferris Decl. ¶ 11. "Current pharmacotherapies offer only symptomatic benefits." Ferris Decl. (PX276) ¶ 13. The disease afflicts more than five million people in the United States and is the sixth leading cause of death in United States. Ferris Decl. ¶ 11; see also Rovner Decl. (PX358) ¶ 20. As the population continues to live longer, the number of people living with Alzheimer's is expected to triple by 2050. Rovner Decl. (PX358) ¶ 20. The visible signs of Alzheimer's include problems with memory and other cognitive functions, social skills, planning, and judgment. Ferris Decl. (PX276) ¶ 11. Patients also develop neuropsychiatric problems including apathy, depression, agitation, and delusions. Ferris Decl. (PX276) ¶ 11; see also

Reisberg Dep. 173:16-24. As the disease progresses, patients become completely dependent on their caregivers as they gradually lose the ability to perform routine activities of daily living. Ferris Decl. (PX276) ¶ 11; Kohrman Dep. 130:25-131:10; Reisberg Hr'g 728:18:729:4. In the final stages of the disease, patients require skilled nursing and intensive supportive care. Ferris Decl. (PX276) ¶ 11; Reisberg Dep. 176:2-177:17.

4. New York in 2014 has about 380,000 people living with Alzheimer's disease, and 1 million non-professional caregivers who provide 1.1 billion hours of care at an unpaid value of $14.3 billion each year. See Alzheimer's Association, 2014 Alzheimer's Disease Facts and Figures, 10 J. Alzheimer's Assoc. e47 (2014) (DX360); Rovner Decl. (PX358) ¶ 21. This caregiving is draining emotionally and physically and becomes more difficult and prolonged because patients with advanced disability can survive many years. Rovner Decl. (PX358) ¶ 21. Most persons with Alzheimer's are cared for at home by spouses and adult children or by professional caregivers in long-term care-facilities. Rovner Decl. (PX358) ¶ 21. About one in seven people with Alzheimer's live alone. Rovner Decl. (PX358) ¶ 23.

5. In 2013, caregivers provided unpaid care valued at more than $220 billion and the burden of providing that care imposed more than $9 billion in additional health care costs on the caregivers themselves. Cremieux ¶ 19 (PX229); Polivka-West Hr'g 621:7-9, 24-25.

B. Number of Prescriptions

6. Although the record does not establish the total number of Namenda prescriptions, the latest estimates are that Namenda IR and Namenda XR each have 50% of the market, as defined below. Defendants' CEO has stated that there are hundreds of thousands of Namenda IR prescriptions. Tr. 242:7-12 (Saunders). A fair approximation of the number of prescriptions is in the neighbor of 500,000. See Tr. 165:15-21 (Stitt).

C. Available Drugs

7. The FDA has approved five drugs to treat Alzheimer's disease: Aricept, Cognex, Exelon, Razadyne, and Namenda, four of which currently are on the market. Lah Decl. (PX85) ¶ 5. Cognex was withdrawn from the market in 2012 because it was toxic. Rovner Dep. 50:23-51:3; Ferris Dep.

96:20-98:14. All these drugs except Namenda are acetylcholinesterase inhibitors ("CIs") and work in the same basic manner. Tr. 53:1-5 (Lah); Lah Decl. (PX85) ¶ 6. CIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. Jacobs Dep. 92:14-93:10; 102:6-19.

8. Namenda is an N-Methyl D-Aspartate ("NMDA") receptor antagonist and works differently from CIs. AC ¶ 47; Tr. 53:10-12; 63:18-64:1 (Lah); Lah Decl. (PX85) ¶ 7; Namenda Franchise Business Plan (PX24) at FRX-NY-01686843 ("CIs work on the acetylcholine pathway while Namenda works on the glutamate pathway."). As Dr. Jacobs explained:

> Neurons in the brain communicate by signaling each other. Some of these signals are transmitted through an influx of calcium into a molecule on the surface of neurons called the NMDA receptor. This influx of calcium is triggered when glutamate, an excitatory neurotransmitter, docks at the NMDA receptor, causing the calcium influx. When patients enter the moderate stage of Alzheimer's disease, there can be overexcitation of the NMDA receptor by glutamate.

Jacobs ¶ 24 (CD Ex. 11); see also Ferris Dep. 99:14-16 (CD Ex. 27). Namenda works by "partially blocking the NMDA receptor to

prevent overexcitation, which can cause toxicity to neurons in the brain." Jacobs ¶ 24 (CD Ex. 11).

9. Currently, the two forms of Namenda produced and sold by Forest, Namenda IR tablets and liquid solution, and Namenda XR capsules, are the only available NMDA receptor antagonists approved to treat Alzheimer's disease. Lah Decl. (PX85) ¶ 7. The active ingredient in both Namenda formulations is memantine HCL. Jacobs ¶ 24 (CD Ex. 11); AC ¶ 47.

D. Stakeholders in the U.S. Healthcare Industry

10. Defendants are one of the complex array of stakeholders comprising the healthcare industry in the United States. See Tr. 368:1-7 (Berndt).

11. Suppliers in this industry include academics and relatively small start-up companies that conduct the initial research necessary to develop medically-promising chemical compounds; large branded pharmaceutical companies such as Forest whose business focuses on developing the medically-promising chemical compounds into saleable patent-protected and FDA-approved medicines, and generic pharmaceutical companies such as Actavis and third-party witness Mylan Pharmaceutical ("Mylan")

whose business focuses on low-cost production of the branded companies' drugs once those medicines have lost patent-exclusivity. See Tr. 236:20-237:20, 246:12-247:06 (Saunders).

12. Depending on the nature of the drug being considered, several intermediaries stand between a supplier and the ultimate end-user, i.e., the patient.

13. One intermediary is the FDA. As the main federal regulator in the industry, the FDA determines which medications can be marketed, whether a drug requires a physician's prescription to be dispensed, and how that drug may be marketed.

14. Another set of intermediaries are physicians and other medical professionals. If the medication is a prescription drug, this group determines which drugs to prescribe, in consultation with their patients. See Tr. 727:3-17 (Reisberg). Pharmacists, either working in traditional brick-and-mortar or mail-order pharmacies, dispense the medications and process payment for the medications. See Kolassa Decl. (DX821) ¶¶ 33, 52.

15. Depending on a patient's morbidity, caregivers comprise yet another group of intermediaries. Caregivers,

whether family members, friends or professional caregivers, may administer or assist the patient in taking the medication.

16. The final group of intermediaries are the third party payors, entities that pay all or part of the costs of a prescription drug on behalf of patients. Kolassa Decl. (DX821) ¶ 31. These include insurance companies and health plans, such as third party witness MVP Health Care ("MVP"). Kolassa Decl. (DX821) ¶ 31; Stitt (PX122) ¶ 4.

17. Typically, third party payors employ several strategies to manage costs. They generate a drug formulary, a list of approved drugs that will be paid for by the health plan (in whole or in part) when an insured patient fills a prescription. Kolassa Decl. (DX821) ¶ 34. A health insurer's drug formulary typically explains what drugs are covered, as well as the level of cost sharing the health plan requires the patient to bear. Kolassa Decl. (DX821) ¶ 34. Pharmacies enjoy larger profit margins on generic versus branded medications. Kolassa Decl. (DX821) ¶ 26.

18. Third party payors sometimes engage pharmacy benefit management companies (PBMs) to assist them in managing

their prescription drug costs. Kolassa Decl. (DX821) ¶ 31 and fn. 27.

19. Third party payors may also require patients to pay a portion of the costs of a drug as a "co-payment" or "co-pay." Kolassa Dep. 156:7-12; Kolassa Decl. (DX821) ¶ 34. This is often accomplished through a tiered co-pay system imposed in conjunction with the formulary file. Kolassa Decl. (DX821) ¶ 37. A typical three-tiered system has tier 1 reserved for generic drugs, tier 2 for preferred branded drugs, and tier 3 for non-preferred branded drugs. Kolassa Decl. (DX821) ¶ 37. The co-pays increase with each tier. Kolassa Decl. (DX821) ¶ 37. Tier 1 co-pays for generic drugs are commonly $10 or less and are sometimes $0. Kolassa Decl. (DX821) ¶ 37. By contrast, tier 3 co-pays for non-preferred brands are commonly between $50 and $90. Kolassa Decl. (DX821) ¶ 37.

20. Step therapy is another third party payor cost savings tool that rejects insurance coverage for a drug until the patient attempts unsuccessfully to take a preferred, usually less costly, alternative for that drug. Kolassa Decl. (DX821) ¶ 41.

21. Finally, third party payors attempt to educate patients and doctors about low-cost alternatives to branded medications, and occasionally implement programs to incentivize doctors and pharmacists to prescribe low-cost drugs. Kolassa Decl. (DX821) ¶¶ 20-21, 28-28.

E. Competition and Regulation

22. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), governs the manufacturing, sale and marketing of pharmaceuticals in the United States. Pursuant to the FDCA, a company seeking to bring a new drug to market must submit a New Drug Application ("NDA") with FDA and provide scientific data demonstrating that the drug is safe and effective. 21 U.S.C. 355(b)(1). The process for obtaining FDA approval of an NDA can be costly and time consuming. Berndt Decl. (PX64) ¶¶ 11-12; Tr. 339:13-18 (Berndt).

23. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, (the "Hatch-Waxman Act"), which was intended to facilitate competition from lower-priced generic drugs while also providing further incentives for pharmaceutical companies by extending

patent protection. Tr. 338:22-340:18 (Berndt); Berndt Decl. (PX64) ¶ 12.

24. By creating benefits, limits, and incentives for both generic and branded pharmaceutical manufacturers, the Hatch-Waxman Act attempted to balance the competing policy goals of encouraging innovation and expediting patient access to less expensive versions of branded drugs. Tr. 338:22-340:18 (Berndt); Berndt Decl. (PX64) ¶ 12; H.R. Rep. No. 98-857, Pt. 1, 14-17 (1984). The Act has been variously characterized as the "grand compromise" between pharmaceutical companies with patent exclusivity and generic manufacturers and as the "thumb on the scales" in favor of generics. Tr. 228:1-12 (Saunders); Tr. 339:19-22 (Berndt).

25. Under the Hatch-Waxman Act, a company seeking to market a generic version of a drug that has an NDA may obtain FDA approval by filing an Abbreviated New Drug Application ("ANDA"), and demonstrating that its generic version is "bioequivalent" to the drug that has an NDA. Tr. 338:19-340:9 (Berndt). By permitting the generic to rely on studies submitted by the NDA applicant (the branded drug manufacturer),

the Act reduces development cost and speeds up FDA approval for generics. Tr. 339:19-340:9 (Berndt).

26. As part of the legislative compromise underlying the Hatch-Waxman Act and its amendments, the Hatch-Waxman Act includes several provisions that grant branded drug manufacturers opportunities to lengthen their exclusivity period beyond the twenty-year term of a patent. The Act allows a branded drug manufacturer to seek up to a five-year patent extension to compensate for time lost during the FDA regulatory process. 35 U.S.C. § 156; Tr. 340:15-340:18 (Berndt); Berndt Decl. (PX64) ¶ 92. In addition, a branded manufacturer may obtain an additional six months of "pediatric exclusivity" after the expiration of the life of its patent, if the manufacturer conducts pediatric studies of its drug that meet certain requirements. 35 U.S.C. § 156; 21 U.S.C. § 355a; Berndt Decl. (PX64) ¶ 92. The Hatch-Waxman Act has twin goals: (i) to encourage generic entry when a branded firm's patent is invalid or not infringed; and (ii) to ensure that the branded firm's patent exclusivity, as well as the branded product's market exclusivity, are appropriately protected. The Hatch-Waxman Act, like the patent laws, incentivizes research by helping to preserve lawful patent and regulatory monopolies, which allows

branded firms to better recover the upfront costs of their innovations, including for drug research and development. AC ¶ 17; Cremieux Decl. (PX229) ¶ 12.

27. State generic substitution laws aim to encourage generic drug sales. New York, prior to the Hatch-Waxman Act enactment in 1984, enacted drug substitution laws that require a pharmacist filling a prescription for a branded drug to substitute a less-expensive, therapeutically equivalent generic drug, unless a physician directs otherwise. See N.Y. Educ. Law § 6816-a; Tr. 115:8-117:4 (Stitt); Tr. 342:13-343:14 (Berndt); Berndt Decl. (PX64) ¶¶ 45-47; Tr. 222:12-222:25 (Saunders). Eleven other states enacted similar legislation. See Tr. 467:16-20 (Berndt); Jesse C. Vivian, Generic-Substitution Laws, U.S. Pharmacist (DX731) (June 19, 2008) at 3 tbl. 2. There are 40 additional states that permit generic substitutions. Id.

28. State substitution laws operate to facilitate lower cost generics because they allow or require a pharmacist to provide a patient with a lower-cost generic drug without contacting the doctor to change the prescription. Tr. 797:19-798:20 (Kolassa). Generics compete on price at the pharmacy and take business from higher-priced brands. Tr. 115:8-117:4

(Stitt); Stitt Decl. (PX122) ¶ 21; Tr. 342:13-343:24 (Berndt); Tr. 897:13-22 (Cremieux). This competition results in reduced drug costs for patients and health plans after generic entry and still provides patients with the same therapeutic benefits as the brand. Tr. 113:16-114:20 (Stitt). An important limitation of generic substitution laws is that they generally permit a pharmacist to dispense a less-expensive generic drug instead of the branded drug only if the FDA approves the generic drug as "AB-rated" to the branded drug. Berndt Decl. (PX64) ¶¶ 45-47; Tr. 342:18-22 (Berndt); Stitt Decl. (PX122) ¶ 21. To be "AB-rated" to a branded drug, the generic drug must not only have the same active ingredient, but also the same form, dosage, strength, and safety and efficacy profile. Zain Decl. Ex. 5 (U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations, Preface (32d ed. 2012)); Tr. 342:2-12 (Berndt).

29. In permissive substitution jurisdictions, managed care organizations and other third party payors encourage generic substitution at the pharmacy, such that any heterogeneity between mandatory and permissive states is negated in practice. Berndt Hr'g 343:11-14 ("And so even though there is variability across states in the specifics of state

substitution laws, in practice there is relatively little heterogeneity.").

30. Price competition at the pharmacy, facilitated by state generic substitution laws, is the principal means by which generics are able to compete in the United States. Tr. 409:6-11 (Berndt); Stitt Decl. (PX122) ¶ 22 ("[T]he substitution of AB-rated generic drugs for the branded equivalents, through the applicability of state generic substitution laws, is the only method by which generic drugs achieve significant sales."); [redacted]; Tr. 351:10-14; 353:1-8; 376:12-17 (Berndt).

31. Generic drugs are usually priced substantially below their brand-name drug equivalents. According to an FDA study using average retail drug prices between 1999 and 2004, entry of multiple generic competitors can reduce prices to as little as 20% of the branded price—in other words, an 80% discount. Tr. 376:12-17 (Berndt).